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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,606	09/23/2003	Xiaoqi Chen	11134-028-999	3424
20583	7590	07/13/2004	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			DESAI, RITA J	
			ART UNIT	PAPER NUMBER
			1625	
DATE MAILED: 07/13/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,606	CHEN ET AL.	
	Examiner	Art Unit	
	Rita J. Desai	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 3-19,34-41,43 and 45-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,20-33,42 and 44 is/are rejected.
- 7) ☒ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>7/9/04</u> . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/24/04</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Priority

The correction to the provisional priority # has been noted.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 11, 1, 2, 5, 7, 9-16, 18, 19, 25, 42, 43 and 44 in part drawn to compounds composition and one method of treating, wherein either X or Y is het atom containing group limited to the combinations given in claim 11., A is a 6 membered aromatic ring, and B is a carbazolyl, classified in class 546,544, 514, subclass 18.
- II. Claims 26 and 1, 2, 20-25, 27-33, 42 and 44 in part drawn to compounds pharmaceutical compositions and *one method of treating* wherein X and Y are independently CH or CH₂ i.e. X and Y is a C1-C2 alkylene, A is a 6 membered artomatic ring and B is a carbazolyl, classified in class 546, 514 subclass 18, 278.
- III. Claims 1-33, drawn to compounds, composition wherein the combinations of the variables are other than those given in Group I or II, classified in various classes and subclasses. A further election of a single disclosed species is required. May be subject to further restriction.

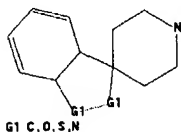
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- IV. Claims 34-42 , drawn to compounds of formula III, VI, IX and XII, classified in various classes and subclasses. A single disclosed species is required. May be subject to further restriction.
- V. Claims 45 –47 , drawn to different methods of treating, classified in class 514 and various subclasses.
- VI. Claims 48-55 , drawn to complex compositions , classified in class 514, 424 and various subclasses.
- VII. Claims 56-63 , drawn to methods of identification using these compounds , classified in various classes and subclasses.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have a different core and hence different bonding and properties.

Also a preliminary search on the core gave numerous iterations indicating that applicants core is not applicants contribution over the prior art.



16.9% PROCESSED 1000 ITERATIONS

50 ANSWERS

INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)

SEARCH TIME: 00.00.01

FULL FILE PROJECTIONS: ONLINE **COMPLETE**

BATCH **COMPLETE**

PROJECTED ITERATIONS: 113906 TO 123134

PROJECTED ANSWERS: 26296 TO 30830

Inventions I-IV and V, VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case there numerous other drugs available which can be used to treat pain asthma and other diseases as listed in the claims. Thus the process for using the product as claimed can be practiced with another materially different product. Restriction is thus proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I or II or III or IV or V or VI or VII , restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Rahul Pathak on 7/8/04 a provisional election was made with traverse to prosecute the invention of Group II , claims 26 and 1, 2, 20-25, 27-33, 42 and 44 in part drawn to compounds pharmaceutical compositions and one method of treating wherein X and Y are independently CH or CH₂ i.e. X and Y is a C₁-C₂ alkylene, A is

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a 6 membered aromatic ring and B is a carbazolyl. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3-19, 34-41, 43, 45-63 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants request to examine Group I and II together is being denied, since the core has so many variables as seen above the search is not co-extensive and hence burdensome.

Applicants preserve their right to file a divisional on the cancelled non-elected subjected matter, without prejudice in due course.

If applicant 's traverse on the grounds that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, 2, 20-25, 27-33, 42 and 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites X and Y independently are (C1-C2) alkylene, and also in formula II R1 and R2 do not have a clear definition of how they would form the compounds as given in claim 26.!

Also with the other different definitions given see below

consisting of (C₁-C₂)alkylene, (C₁-C₂)alkylene-OR³,
(C₁-C₂)alkylene-N(R³)COR⁴, (C₁-C₂)alkylene-C(O)NR³R⁴,
(C₁-C₂)alkylene-N(R³)CO₂R⁴, (C₁-C₂)alkylene-N(R³)C(O)N(R⁴)R⁵,
(C₁-C₂)alkylene-C(O), O, C(O), N(R³), C(O)N(R³), S(O)_k and SO₂N(R³);
R¹ and R² are independently selected from the group consisting of H,
(C₁-C₄)alkyl, (C₂-C₈)alkenyl, (C₂-C₈)alkynyl, (C₁-C₈)heteroalkyl, aryl,
aryl(C₁-C₄)alkyl, NR⁶C(O)R⁵, C(O)R⁵ and NR³C(O)NR⁶;

It is unclear where the point of attachment is to the ring.!

Applicants may be able to overcome this by just including the specific species as given in their examples in claim 26, so as not to introduce new matter.

Claim 26 recites the limitation of "OH" and the various substituents of the 5 and 6 membered spiro ring. There is insufficient antecedent basis for this limitation in the claim 25 or 1 since X and Y are not clearly defined to include such attachments.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 44 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antagonist activity of MCHR2, does not reasonably provide enablement for treating all the various diseases as given in the claim. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

There are numerous factors to be considered for enablement.

The state of the art of treating diseases is highly unpredictable, and drugs do not have an umbrella efficacy of treating many diseases as listed in claim 44.

Applicants can overcome this by limiting the claim to the elected One method of treating.

Claims 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite prodrugs and there is no description as to what these prodrugs actually are. The specification just describes it as a compound which invivo gets converted to the compound of claim 1, without describing as to what they really are. Applicants can overcome this by deleting the term prodrug from the claims.

Conclusion

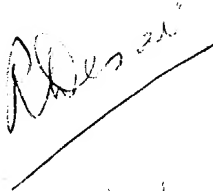
The claims are free from the prior art of record.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rita J. Desai
Primary Examiner
Art Unit 1625



R.D.
July 9, 2004